Modafinil (Provigil)

Prior Authorization Criteria for the TRICARE Pharmacy (TPHARM) Program

Background

Modafinil (Provigil) is approved by the FDA for treatment of excessive daytime sleepiness associated with narcolepsy, excessive daytime sleepiness associated with obstructive sleep apnea/hypopnea syndrome (OSAHS) when used as an adjunct to continuous positive airway pressure (CPAP) treatment, and excessive daytime sleepiness associated with shift-worker sleep disorder (SWSD). There are numerous off-label uses. Off-label uses identified by the DoD P&T Committee as supportable based on published clinical evidence or recommendations from nationally recognized expert organizations, based on TRICARE regulations (TRICARE Policy Manual 6010.54 [August 2002] chapter 1 section 2.1) regarding coverage of unproven drugs, devices, medical treatments and procedures, are included in the criteria below. Other off-label uses are supported only by case reports, uncontrolled trials, single-blinded trials, or chart reviews, which constitute insufficient evidence to establish efficacy and safety.

The following criteria were established by the DoD Pharmacy & Therapeutics (P&T) Committee. The effective date for this prior authorization is 18 April 2007. This prior authorization approval is good for 1 year.

Prior Authorization Criteria for Modafinil (Provigil)

Coverage is provided for the use of modafinil for the treatment of:

- Excessive daytime sleepiness associated with narcolepsy ; as diagnosed by polysomnogram or MSLT objective testing
- Excessive daytime sleepiness associated with obstructive sleep apnea/hypopnea syndrome (OSAHS), only after adequate titration of continuous positive airway pressure (CPAP) treatment
- Excessive sleepiness associated with shift-worker sleep disorder (SWSD), only in patients who work night shifts
- Excessive fatigue associated with multiple sclerosis, only after secondary causes of fatigue have addressed
- Excessive fatigue associated with myotonic dystrophy
- Depression, only after primary therapy has failed and if the use of other stimulant augmentation is contraindicated
- Idiopathic hypersomnia diagnosed by a sleep specialist
- Fatigue associated with mild traumatic brain injury

NOTE: this prior authorization is not intended to apply to modafinil use in active duty operational/readiness situations based on established protocols; Military Treatment Facilities should make necessary allowances such use.

Coverage is **not** provided for the use of modafinil (Provigil) for the treatment of other conditions, including:

- Chronic fatigue syndrome
- Stroke rehabilitation
- Appetite suppression
- Parkinson's disease

Criteria approved through the DoD P&T Committee process Jan 2007, revised November 2009